

C/Er.

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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Annie TUMMINO, *et al.*,

Plaintiff

- against -

Andrew C. von ESCHENBACH, as Acting  
Commissioner of the Food and Drug  
Administration,

Defendant  
-----X

CV-05-366 (ERK) (VVP)

**MEMORANDUM**

**FILED**

IN CLERK'S OFFICE  
U.S. DISTRICT COURT, E.D.N.Y.

★ AUG 7, 2006 ★

BROOKLYN OFFICE

KORMAN, Chief Judge.

In light of the comments of the Assistant United States Attorney at the status conference on July 26, 2006, regarding the feasibility of providing Plan B behind-the-counter for those 18 years of age and older, I call the attention of the parties to the enclosed Reuters article regarding the FDA's plan to allow Plan B pills to be sold behind pharmacy counters for sale for women over the age of 18.

Brooklyn, New York  
July 31, 2006

s/Edward R. Korman  
\_\_\_\_\_  
Edward R. Korman  
United States District Judge



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July 31, 2006

## FDA May Loosen "Morning - After Pill" Sales

By REUTERS

Filed at 2:11 p.m. ET

WASHINGTON (Reuters) - Non-prescription sales of a "morning-after" contraceptive could be approved for women 18 and older within weeks, U.S. health officials said on Monday in a surprise announcement after years of delays.

Barr Pharmaceuticals Inc.'s Plan B pills would be kept behind pharmacy counters and women would need to ask for them, a Food and Drug Administration official said. Anyone younger than 18 still would need a prescription.

"If the conversations go smoothly and everyone works expeditiously through this, we think this is something that could be wrapped up in a matter of weeks, not months," said the FDA official, who asked not to be named.

The sudden shift came one day before Acting FDA Commissioner Andrew von Eschenbach is set to appear before a Senate committee considering his nomination to become the agency's permanent chief.

Two Senate Democrats said they still intended to block a vote on von Eschenbach's nomination unless the agency makes a final decision on whether to approve over-the-counter Plan B sales.

"Today's announcement is nothing more than another delay tactic. The FDA continues to shirk its duty to serve as an independent agency dedicated to no other goal than the promotion of sound science and the well-being of the American people," Sens. Patty Murray of Washington and Hillary Rodham Clinton of New York said in a statement.

In August 2005, the FDA indefinitely postponed a decision, sparking an outcry that the agency had let opposition from political conservatives overrule science. An FDA advisory panel had recommended over-the-counter sales in December 2003.

Some conservatives say easy access to Plan B could lead to greater promiscuity, particularly among teenagers. The pills can prevent pregnancy if taken within 72 hours of sexual intercourse.

Women's groups say over-the-counter sales could reduce the number of abortions because more women would be

able to get the pills in time without going through the hurdles of getting a prescription.

Barr had sought to sell Plan B over the counter to females age 16 and older, but FDA officials felt evidence was lacking that younger women could take the pills safely and now believe 18 is the appropriate age for non-prescription sales, the FDA official said.

Barr spokeswoman Carol Cox said the company would meet the FDA within seven days as requested.

"I'd say it's a positive development that they would like to meet with us. We'll have to wait until we meet with them to see what they require from us and what kind of timeline we can work forward on," Cox said.

Plan B is a set of two pills, that contain higher doses of a hormone used in birth control pills, taken 12 hours apart to block the release or fertilization of an egg.

It is different from the RU-486 "abortion pill," which can terminate an early pregnancy by blocking a hormone that keeps a fertilized egg implanted in the uterus.

Barr shares gained 2 percent to \$49.81 in early afternoon trading on the New York Stock Exchange.

Barr shares hit a 52-week intraday high in February of \$70.25 after reporting robust earnings but went as low as \$44.61 earlier this month amid general pessimism about the outlook for generic drug makers.

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